IMPLANTABLE MEDICAL DEVICE FOR CONTROLLED RELEASE OF A SUBSTANCE

FIELD OF THE INVENTION

The invention is in the field of implantable medical devices. More specifically, the invention relates to such devices controlled release of a substance in a body cavity such as a urinary bladder or digestive tract organ.

BACKGROUND OF THE INVENTION

There are many instances when it is desirable to release a substance in a body cavity over a prolonged period of time.

US Patent No. 6,364,856 to Ding et al., for example, discloses medical devices comprising an expandable portion which is covered with a sponge coating for releasing a biologically active material. The sponge coating is made of a non-hydrogel polymer having a plurality of voids. The device can further include means for infusing or expelling the biologically active material or drug into the voids. The drug is delivered to the body lumen of a patient by expelling the drug and inflating or expanding the expandable portion of the catheter or device.

US Patent No. 6,187,038 to Sullivan *et al.*, discloses a composite graft for a blood vessel comprising: an inner vessel made of a biologic collagenic material

and an outer sleeve surrounding the inner vessel and defining an annular gap between the inner vessel and the sleeve. A polymeric fabric, and a bioactive compound in the annular gap carried on a time-release vehicle.

US Patent 6,187,768 to Harle discloses corpuscles for implantation into or at body tissue. Medicine is distributed in carriers formed of biologically inert material for release into body tissue after implantation. The surface-to-volume ratio of the carriers is more satisfactory than that of the carriers forming part of conventional corpuscles so that they are readily withdrawn from the body.

US Patent Nos. 6,293,923 and 6,398,718 to Yachia et al describe devices for insertion into a urinary bladder that may be adapted to release a substance in the bladder.

While some prior art devices allow the rate at which a substance is released from the device to be determined, prior art devices do not allow the release of the substance to be started and stopped repeatedly over time as may be required in any particular application.

In its first aspect, the invention thus provides a medical device for controlled release of one or more substances into a body cavity containing an electrolytic fluid comprising:

(a) a power supply having first and second terminals;

(b) a plurality of blister-like vesicles mounted on a first surface, each vesicle having at least a metallic portion formed from a first metal;

(c) for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed; and

(d) A cathode formed from a second metal attached to the second terminal of the power supply;

wherein the cathode is separated from the anodes by a space that is assessable by the electrolytic fluid when the device is in the body cavity.

In its second aspect, the invention thus provides a system for treating a body cavity of an individual, the system comprising:

(a) a device according to the invention and

(b) an applicator for inserting the device into the body or for removing the device from the body cavity, the applicator fitted at an end thereof with a gripping device for releasably gripping the device;

In its third aspect, the invention thus provides a system for treating a body cavity of an individual, the system comprising:

(a) a device according to the invention;

(b) an applicator for inserting the device into the body or for removing the device from the body cavity, the applicator fitted at an end thereof with a gripping device for releasably gripping the device; and

(c) an inflating device for inflating the balloon.

In its fourth aspect, the invention thus provides a method for releasing one or more substances into a body cavity containing an electrolytic fluid of an individual comprising the steps of:

(a) loading the one or more substances into the vesicles of a device according to the invention;

(b) inserting the device into the body cavity;

(c) expanding the balloon in the urinary bladder; and

(d) displacing the balloon within the urinary bladder to a desired location.

In its fifth aspect, the invention thus provides a method for releasing one or more substances into a body cavity containing an electrolytic fluid of an individual comprising the steps of:

(a) loading the one or more substances into the vesicles of a device according to the invention;

(b) inserting the device into the body cavity; and

(c) expanding the balloon in the body cavity.

BRIEF DESCRIPTION OF THE DRAWINGS:

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a device for releasing substances in a body cavity in accordance with one embodiment of the invention;

Fig. 2 shows a device for releasing substances in a body cavity in accordance with another embodiment of the invention;

Fig. 3 shows the embodiment of Fig. 2 mounted on an inflatable balloon;

Fig.4 shows the balloon of Fig. 3 without the device;

Fig. 5 shows a portion of a balloon having a duck-bill valve;

Fig. 6 shows a portion of a balloon according to the invention having a ball valve;

Fig. 7 shows a device-balloon combination in which the balloon filled after have been inserted into body cavity;

Fig. 8 shows a device-balloon combination in which the balloon is filled before being inserted into the urinary bladder;

Fig. 9 shows use of an applicator for inserting a device-balloon combination into the urinary bladder of a female individual;

Fig. 10 shows use of an applicator for inserting a device-balloon combination into the urinary bladder of a male individual;

Fig. 11 shows a retrieval device for retrieving a device-balloon combination;

Fig. 12 shows use of a displacing member to position a device-balloon combination in a desired position in a body cavity; and

Fig. 14 shows use of an immobilizing member.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Reference is now made to Fig. 1 which shows a first embodiment 100 of a device for controlled released of a substance or substances into a body cavity in accordance with the invention. A plurality of blisters **105** are mounted on a first

surface **110** of the device. The first surface **110** is formed from an insulating material such as rubber. Each blister **105** has a wall **115** surrounding a lumen **120.** The lumen **120** of each blister is filled with the one or more substances (not shown) that are to be released into the body cavity. The wall **115** of each blister may be made entirely of metal, or may have a metallic portion. In the embodiment shown in Fig. 1, each blister has a metallic portion **125** that is referred to herein as the *"anode"*. A second surface **130** of the device (referred o herein as the *"cathode"*) **100** is formed from a second metal.

The device further comprises a power supply **135.** Each anode **125** is connected to a first terminal **140** of the power supply **135** via an individual electrical connection **145.** The connection **145** includes a switch **150.** The cathode **130** is connected to the second terminal of the power supply **135.**

The device may further include a processor **155** that is connected to each of the switches **145** by an individual connection **160** and is configured to close each switch at a predetermined time. For example, the processor **155** may be configured to close one switch every four hours, or some other predetermined time. Alternatively, the switches may be closed by means of a remote control located outside the body (not shown). For example, the user may be instructed to use the remote control to close a switch every evening before going to bed. AS yet another example, the device 100 may include one or more detectors (not shown) for monitoring conditions within the body cavity that are input to the processor, the processor closing a switch under predetermined conditions inside the body cavity.

The device **100** may also include a magnet **165** in order to allow the device **100** to be positioned in the body cavity by means of a second magnet located outside the body (not shown).

Fig. 2 shows another embodiment **200** of the invention. In this embodiment a plurality of blisters **205** are mounted on a cylindrical surface **210**. The cylindrical surface **210** is formed from an insulating material such as rubber. Each blister **205** has a wall **215** surrounding a lumen **220.** The lumen **220** of each blister is filled with the one or more substances (not shown) that are to be released into the body

cavity. The wall **215** of each blister may be made entirely of metal, or may have a metallic portion. In the embodiment shown in Fig. 2, each blister has a metallic portion **225** that is referred to herein as the *"anode"*.

In the interior of the cylindrical surface **210** is a power supply **235.** Each anode **225** is connected to a first terminal **240** of the power supply **235** via an individual electrical connection **245.** The connection **245** includes a switch **250.**

The interior of the cylindrical surface may further include a processor **255** that is connected to each of the switches **245** by an individual connection **260** and is configured to close each switch at a predetermined time. Alternatively, the switches may be closed by means of a remote control located outside the body (not shown).

Surrounding the cylindrical surface **240** is a cylindrically shaped cathode **230** that is coaxial with the cylindrical surface **240.** This arrangement is maintained by means of rigid radial rods 270. The cathode **230** is formed from a second metal, and preferably has a mesh-like structure. The cathode **230** is connected to the second terminal of the power supply **135.** The

The device **200** may also include a magnet **265** in order to allow the device **200** to be positioned in the body cavity by means of a second magnet located outside the body (not shown).

As shown in Fig. 3, the device **200** may be mounted on an inflatable balloon **301.** The balloon **302** made of a bio-compatible material enclosing a lumen **204.** The inflated balloon may have any desired shape as required in any particular application. In a preferred embodiment, the balloon **301** has a torroidal shape as shown in Fig. 3. The balloon **301** is shown in Fig. 4 without the device **200** being mounted in it. The balloon encircles a cylindrical hole **400** that is dimensioned to receive the device **200.** The device **200** is firmly set in the hole 400 by means of pressure exerted on the device **200** by the wall **202** of the balloon **301** when inflated.

The lumen **304** of balloon **301** may be filled with a bio-compatible fluid which may be pre-sterilized such as air, water, saline or an oil such as liquid

paraffin. The balloon **301** may further comprise a magnetizable portions (not shown) in order to position the device in the body cavity by means of n external magnet. The magnetizable portion may consist for example, of one or more metal particles which may be free in the lumen **304,** attached to the inner surface of the wall **302or** embedded in the wall **302.**

A self-sealing valve **305** in the wall of the balloon is used to fill the balloon. The valve **305** may be for example a duck-bill type valve as shown in Fig. 5, or a ball valve as shown in Fig. 6 in which a ball **508** may be in a sealing position (Fig. 6a) or an unsealing position (Fig. 6c). The canula **506** of a syringe **507** is inserted through the valve **305** into the lumen **304** of the balloon. Fluid injected into the lumen **304** causes the balloon **301** to expand. After filling, the syringe needle **506** is withdrawn, and the valve **305** seals itself. The inflated balloon with the device **200** mounted on it may float or sink in the electrolytic liquid in the body cavity. .

As shown in Fig. 7, the device-balloon combination **308** may first be delivered to the body cavity with the balloon **301** deflated, by means of an applicator **720** to be described below in detail (Fig. 7a). Following release of the device-balloon combination **308** from the applicator **720** into the cavity, the balloon **301** is filled with fluid **724** from the syringe **507** (Fig. 4b). Alternatively, as shown in Fig. 8a, the balloon **301** of the device-balloon combination **308** may be filled with a compressible fluid. The balloon **301** is then compressed before being inserted into the bladder by means of an applicator **820.** The devie-balloon combination **308** with the pre-filled balloon is clutched by the flanges **823** which are initially kept closed by constraining sleeve **826** (Fig. 5a). After insertion of the applicator **820** with the device-balloon combination **308** into the body cavity, ring **825** is pulled as indicated by arrow **121** in Fig. 8b to urge the constraining sleeve **826** away from the flanges **823,** allowing flanges **823** to open and release the device-balloon combination **308** with the pre-filled balloon **301** into the body cavity.

Fig. 9 shows use of an applicator **920** for inserting the device-balloon combination **308** into the lumen **941** of a urinary bladder **942** of a female individual, and Fig. 10 shows use of the applicator **920** inserting the device-balloon combination 308 into the lumen of the urinary bladder **942** of a male individual. In either case the device-balloon combination **308** is initially grasped by the closed flanges **923a** at the distal end of the applicator **920** (Figs. 9a and 10a). The distal end of the applicator with the device-balloon combination 308 is inserted into the urethra until it reaches the lumen **941** of the bladder **942.** The device-balloon combination 308 is then released from the applicator by opening the flanges **923b** by pulling on ring **925** while holding the constraining sleeve **926.** The applicator **920** is then removed from the body, leaving the device-balloon combination in the bladder lumen **41**.

Fig. 11 shows a retrieval device generally designated as **930** for removing the device-balloon combination 308 from a body cavity. A catheter **927** has at its distal end **928** a magnetizable portion **929** so as to hold the device-balloon combination **308** at the distal tip **928** by means of the magneiztable particles associated with the balloon **301** or the device **200.**

The retrieval device **930** is inserted into the body cavity. After opening the flanges **831** of the retrieval device, the engaging probe **932** with magnetizable portion **929** in its tip is inserted into the body cavity so as to engage a magnet associated with either the device **200** or the balloon **301.** The probe **932** is then pulled so as to bring the balloon **301** into the grip of flanges **831** of the retrieval device **930.** A piercer **933** is inserted into the balloon **301** to drain the fluid **724** contained in its lumen **304** into an attached syringe (not shown) or into the body cavity. The retrieval device **930** is then withdrawn from the individual together with the device **200** and the deflated balloon **301.**

Fig. 12 shows use of a displacing member **951** to position the device-balloon combination 308 at a desired location in the body cavity. The displacing member **951** is located outside the individual's body and comprises a magnetizable

portion **952.** The displacing member **951** is placed at a location on the surface of the individual's body so as to draw the device balloon combination to a desired location within the body cavity.

Fig. 13 shows use of an immobilizing member **971** comprising a magnetizable portion **972** affixed to the surface **973** of the individual's body so as to maintain the device-balloon combination 308 at the desired location in the body cavity. The magnetizable portion **972** of immobilizing member **971** may be enclosed in a coating **975** so as to form, for example, a hygienic pad. The immobilizing member **971** may be affixed to the surface **73** by means of tape, or may be incorporated into a garment worn by the individual.

The invention has been described with a certain degree of particularly only for the sake of clarity. However, several variations and modifications in the invention are possible without exceeding the scope and spirit of the invention as defined in the following set of claims.